106TH CONGRESS
1ST SESSION

# H. R. 2769

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to permit individuals to continue health coverage of services while participating in approved clinical studies.

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IN THE HOUSE OF REPRESENTATIVES

AUGUST 5, 1999

Mrs. LOWEY introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committees on Education and the Workforce, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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# A BILL

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to permit individuals to continue health coverage of services while participating in approved clinical studies.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the "Improved Patient Access to Clinical Studies Act of 1999".

**SEC. 2. CONTINUING COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL STUDIES.**

(a) GROUP HEALTH PLANS.—

(1) PUBLIC HEALTH SERVICE ACT AMENDMENTS.—(A) Subpart 2 of part A of title XXVII of the Public Health Service Act is amended by adding at the end the following new section:

**"SEC. 2707. CONTINUING COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL STUDIES.**

"(a) PERMITTING PARTICIPATION IN APPROVED CLINICAL STUDIES.—A group health plan, and a health insurance issuer offering group health insurance coverage—

"(1) may not deny (or limit or impose additional conditions on) coverage of items and services furnished to a participant or beneficiary if—

"(A) the participant or beneficiary is participating in an approved clinical study;

"(B) the items and services are furnished according to the design of the study or to treat conditions resulting from participation in the study; and

"(C) the items and services would otherwise be covered under the plan except for the

fact that they are provided in connection with participation in such a study; and

"(2) may not discriminate against a participant or beneficiary on the basis of the participant's or beneficiary's participation in such a study.

"(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed as requiring a group health plan or health insurance issuer to provide for payment for items and services normally paid for as part of an approved clinical study.

"(c) NOTICE.—A group health plan under this part shall comply with the notice requirement under section 714(c) of the Employee Retirement Income Security Act of 1974 with respect to the requirements of this section as if such section applied to such plan.

"(d) APPROVED CLINICAL STUDY DEFINED.—In this section, the term 'approved clinical study' means—

"(1) a research study approved by the Secretary of Health and Human Services, the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, the Secretary of Veterans Affairs, the Secretary of Defense, or a qualified nongovernmental research entity (as defined in guidelines of the National Institute of Health); or

"(2) a peer-reviewed and approved research program, as defined by the Secretary of Health and Human Services, conducted for the primary purpose of determining whether or not a treatment is safe, efficacious, or having any other characteristic of a treatment which must be demonstrated in order for the treatment to be medically necessary or appropriate.".

(B) Section 2723(c) of such Act (42 U.S.C. 300gg–23(c)) is amended by striking "section 2704" and inserting "sections 2704 and 2707".

(2) ERISA AMENDMENTS.—(A) Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following new section:

**"SEC. 714. CONTINUING COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL STUDIES.**

"(a) PERMITTING PARTICIPATION IN APPROVED CLINICAL STUDIES.—A group health plan, and a health insurance issuer offering group health insurance coverage—

"(1) may not deny (or limit or impose additional conditions on) coverage of items and services furnished to a participant or beneficiary if—

"(A) the participant or beneficiary is participating in an approved clinical study;

"(B) the items and services are furnished according to the design of the study or to treat conditions resulting from participation in the study; and

"(C) the items and services would otherwise be covered under the plan except for the fact that they are provided in connection with participation in such a study; and

"(2) may not discriminate against a participant or beneficiary on the basis of the participant's or beneficiary's participation in such a study.

"(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed as requiring a group health plan or health insurance issuer to provide for payment for items and services normally paid for as part of an approved clinical study.

"(c) NOTICE UNDER GROUP HEALTH PLAN.—The imposition of the requirement of this section shall be treated as a material modification in the terms of the plan described in section 102(a)(1), for purposes of assuring notice of such requirements under the plan; except that the summary description required to be provided under the last sentence of section 104(b)(1) with respect to such

modification shall be provided by not later than 60 days after the first day of the first plan year in which such requirement apply.".

"(d) APPROVED CLINICAL STUDY DEFINED.—In this section, the term 'approved clinical study' means—

"(1) a research study approved by the Secretary of Health and Human Services, the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, the Secretary of Veterans Affairs, the Secretary of Defense, or a qualified nongovernmental research entity (as defined in guidelines of the National Institute of Health); or

"(2) a peer-reviewed and approved research program, as defined by the Secretary of Health and Human Services, conducted for the primary purpose of determining whether or not a treatment is safe, efficacious, or having any other characteristic of a treatment which must be demonstrated in order for the treatment to be medically necessary or appropriate.".

(B) Section 731(c) of such Act (29 U.S.C. 1191(c)) is amended by striking "section 711" and inserting "sections 711 and 714".

(C) Section 732(a) of such Act (29 U.S.C. 1191a(a)) is amended by striking "section 711" and inserting "sections 711 and 714".

(D) The table of contents in section 1 of such Act is amended by inserting after the item relating to section 713 the following new item:

"Sec. 714. Continuing coverage for individuals participating in approved clinical studies.".

(3) INTERNAL REVENUE CODE AMENDMENTS.—

(A) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended—

(i) in the table of sections, by inserting after the item relating to section 9812 the following new item:

"Sec. 9813. Continuing coverage for individuals participating in approved clinical studies."; and

(ii) by inserting after section 9812 the following:

**"SEC. 9813. CONTINUING COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL STUDIES.**

"(a) PERMITTING PARTICIPATION IN APPROVED CLINICAL STUDIES.—A group health plan—

"(1) may not deny (or limit or impose additional conditions on) coverage of items and services furnished to a participant or beneficiary if—

"(A) the participant or beneficiary is participating in an approved clinical study;

"(B) the items and services are furnished according to the design of the study or to treat conditions resulting from participation in the study; and

"(C) the items and services would otherwise be covered under the plan except for the fact that they are provided in connection with participation in such a study; and

"(2) may not discriminate against a participant or beneficiary on the basis of the participant's or beneficiary's participation in such a study.

"(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed as requiring a group health plan to provide for payment for items and services normally paid for as part of an approved clinical study.

"(c) APPROVED CLINICAL STUDY DEFINED.—In this section, the term 'approved clinical study' means—

"(1) a research study approved by the Secretary of Health and Human Services, the Director of the National Institutes of Health, the Commis-

sioner of the Food and Drug Administration, the Secretary of Veterans Affairs, the Secretary of Defense, or a qualified nongovernmental research entity (as defined in guidelines of the National Institute of Health); or

"(2) a peer-reviewed and approved research program, as defined by the Secretary of Health and Human Services, conducted for the primary purpose of determining whether or not a treatment is safe, efficacious, or having any other characteristic of a treatment which must be demonstrated in order for the treatment to be medically necessary or appropriate.".

(B) CONFORMING AMENDMENT.—Section 4980D(d)(1) of such Code is amended by striking "section 9811" and inserting "sections 9811 and 9813".

(b) INDIVIDUAL HEALTH INSURANCE.—(1) Part B of title XXVII of the Public Health Service Act is amended by inserting after section 2752 the following new section:

"SEC. 2753. CONTINUING COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL STUDIES.

"(a) IN GENERAL.—The provisions of section 2707 (other than subsection (c)) shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as they apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market.

"(b) NOTICE.—A health insurance issuer under this part shall comply with the notice requirement under section 714(c) of the Employee Retirement Income Security Act of 1974 with respect to the requirements referred to in subsection (a) as if such section applied to such issuer and such issuer were a group health plan.".

(2) Section 2762(b)(2) of such Act (42 U.S.C. 300gg–62(b)(2)) is amended by striking "section 2751" and inserting "sections 2751 and 2753".

(c) EFFECTIVE DATES.—

(1) GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE.—Subject to paragraph (3), the amendments made by subsection (a) apply with respect to group health plans for plan years beginning on or after January 1, 2000.

(2) INDIVIDUAL HEALTH INSURANCE COVERAGE.—The amendments made by subsection (b) apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after such date.

(3) COLLECTIVE BARGAINING EXCEPTION.—In the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and 1 or more employers ratified before the date of enactment of this Act, the amendments made subsection (a) shall not apply to plan years beginning before the later of—

(A) the date on which the last collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of enactment of this Act), or

(B) January 1, 2000.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by subsection (a) shall not be treated as a termination of such collective bargaining agreement.

(d) COORDINATION OF ADMINISTRATION.—The Secretary of Labor, the Secretary of the Treasury, and the Secretary of Health and Human Services shall ensure, through the execution of an interagency memorandum of understanding among such Secretaries, that—

(1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which two or more such Secretaries have responsibility under the provisions of this Act (and the amendments made thereby) are administered so as to have the same effect at all times; and

(2) coordination of policies relating to enforcing the same requirements through such Secretaries in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement.

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